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February 2013 Meeting Report and Update

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COUNCIL ON GOVERNMENTAL RELATIONS

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March 15, 2013

February 21 and 22, 2013 Meeting Report and Update

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COSTING POLICIES

Committee: Susan Camber, Chair, University of Washington; James Barbret, Wayne State University; Cynthia Hope, University of Alabama; James Luther, Duke University; James R. Maples, University of Tennessee; Kim Moreland, University of Wisconsin – Madison; John Shipley, University of Miami; Eric Vermillion, University of California, San Francisco; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; Dan Evon, Michigan State University; Terry Johnson, University of Iowa; Cathy Snyder, Vanderbilt University; Pamela Webb, University of Minnesota

The Federal Budget and Sequestration

Sequestration was enacted on March 1st and requires \$85 billion in Federal spending cuts for the remainder of FY2013 (i.e., thru September 30, 2013). Federal agencies have begun notifying award recipients of agency plans to implement the required budget cuts. The three links below are: 1) NIH Operations Under the Sequester (March 4, 2013); 2) NSF Impact of FY2013 Sequestration Order (February 27, 2013), and 3) OMB Memorandum on Agency Responsibilities (February 27, 2013).

<http://nexus.od.nih.gov/all/2013/03/04/nih-operations-under-the-sequester/>

<http://www.nsf.gov/pubs/2013/in133/in133.jsp>

<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-05.pdf>

Resolution to the Sequestration is uncertain. Intimately tied to any resolution is the status of the FY2013 Continuing Resolution currently funding the Federal government (in effect through March 27, 2013) and the latest political posturing on the FY2014 Federal budget. It is a distinct possibility Sequestration will not be resolved as it relates to the FY2013 budget cuts. Subsequently, at issue will be the impact of Sequestration on the FY2014 budget, and at this stage, outcomes are unpredictable. We will continue to share information with the membership as we learn more.

Grants Reform and the Proposed OMB Uniform Guidance

The much anticipated “*Proposed OMB Uniform Guidance: Cost Principles, Audit, and Administrative Requirements for Federal Awards*” was released last month. The February 1, 2013 – Federal Register Notice can be found at:

<http://www.gpo.gov/fdsys/pkg/FR-2013-02-01/pdf/2013-02113.pdf>

In support of the Proposed Guidance, OMB has provided a number of documents that can be accessed at the following website:

http://www.whitehouse.gov/omb/grants_docs#proposed

Included on the OMB website is a link to a Summary of Changes document (i.e., the same text as the Federal Register Notice referenced above), a link to the FULL TEXT (i.e., the Proposed Guidance), and six additional links to various crosswalks between the current circulars and the Proposed Guidance.

The FULL TEXT is a 241 page document (or a 244 page document if you downloaded the initial posting) that consolidates Administrative Requirements (Circulars A-110, A-102, A-89), Cost Principles (Circular A-21, A-87, A-122), and Audit Requirements (Circulars A-133, A-50) into a single document. Pending a possible future review, the Cost Principles for Hospitals (*Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals*) that are in the regulations of the Department of Health and Human Services (45 CFR Part 75, Appendix E) may be addressed at a later date.

The 241 page FULL TEXT is presented in a logical manner, which in COGR's view, has been completed in a format that is relatively easy to follow. The crosswalk and definition documents that are available at the OMB website are helpful supplements. The February 1, 2013 – Federal Register Notice, which is a high-level summary of the proposed changes, addresses many of the comments that COGR made in its response to the February 28, 2012 – Federal Register, Advance Notice of Proposed Guidance (ANPG): *Reform of Federal Policies Relating to Grants and Cooperative Agreements: Cost Principles and Administrative Requirements (including Single Audit Act)*.

The Proposed Guidance, at this point, will be open for a 90-day public comment period and comments can be submitted at regulations.gov under docket number OMB-2013-0001. If the 90-day public comment period is not extended, the due date for comments will be Midnight EST, May 2, 2013.

30-Day Extension Requested by COGR

COGR has requested a 30-day extension to submit comments. The consensus among those members from the COGR Costing Policies and RCA committees who are active in developing the COGR Response is that a 30-day extension is necessary to craft the most thorough response. On the other hand, asking for more than a 30-day extension has the potential for distracting from the sense of urgency. We are cautiously optimistic that the extension will be granted and we will update the membership posted as soon as we learn more.

COGR Assessment and COGR Gameplan for Responding to the Proposed Guidance

The February 21-22 COGR Meeting provided the perfect timing for sharing preliminary assessments and discussions with the COGR membership. At one of the Thursday morning sessions, members from the COGR Costing Policies and RCA committees led a dialogue on the Proposed Guidance. Mike Ludwig (Purdue University) addressed the Administrative Requirements, Mary Lee Brown (University of Pennsylvania) focused on the Audit Requirements, and Cindy Hope (University of Alabama) and Jim Luther (Duke University) spoke to the Costing Principles. The PPT presentations are available at www.cogr.edu (see Meetings | February 2013 Meetings Presentations tab).

OMB Controller, Danny Werfel, in one of the Thursday afternoon sessions, provided the COGR membership with an inside view of the Proposed Guidance and answered questions from the COGR membership. Mr. Werfel emphasized OMB's commitment to work with the grantee community during the response period, after responses are submitted, and during implementation of the final OMB guidance. OMB hopes to release final guidance before the end of the 2013 calendar year. While COGR is committed to being a supportive partner of OMB, we will share our concerns with OMB if we believe the release of final guidance could be premature.

The *COGR Preliminary Assessment of Selected Items* was sent to the COGR ListServe on Friday, March 8th. In the email to the ListServe, we emphasized "preliminary" and "selected." Members of the COGR Costing and RCA committees, plus several at-large members who have volunteered to help, have formed seven topical workgroups and are actively meeting and addressing the entire 241 pages of the Proposed Guidance. As we meet and review the Proposed Guidance, we continue to uncover items that will need to be addressed in the final COGR Response. The *COGR Preliminary Assessment of Selected Items* is available at www.cogr.edu (see Latest News!, March 7, 2013, on the Home Page).

Assuming OMB grants a 30-day extension to June 1st (see previous section), we are targeting to make available a Draft Version of the COGR Response approximately April 19th. We expect to comment on a section-by-section basis of the Proposed Guidance, which will include proposed revised language and justifications as to why the language should be updated. Your institution will be able to use the Draft Version to formulate and/or fine-tune your institutional responses.

It will be a major community effort to develop this response – and in addition to the COGR Response, your institutions also will submit responses to OMB. The formal COGR Gameplan, in combination with the experience and expertise of the COGR membership, will be crucial to an effective COGR Response – we will rely on your observations as you independently read through the Proposed Guidance. Please forward your input and questions to dkennedy@cogr.edu.

We look forward to working with your institutions on this effort over the next several months and we will keep you posted on all developments.

NIH and Costing for Core Facilities – FAQs to be Released Soon

Our understanding is that the release of the NIH FAQs addressing the Costing for Core Facilities is imminent and that we should see these within the next few weeks. In the past two COGR Updates (February 2013 Update - February 5, 2013 and the COGR Holiday Update - December 20, 2012), we provided the background and status on this NIH initiative, which began with a September 2010 NIH Notice Number (NOT-OD-10-138, see link below).

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-138.html>

In November, NIH shared with COGR a revised set of FAQs based on our community's input to the 2010 NIH Notice. Consequently, NIH asked COGR (and others from the research community) to provide feedback on the revised FAQs. COGR comments to the revised FAQs were in the form of a "red-lined version" and COGR submitted these to NIH on December 20th.

The “red-lined version” (including the Cover Letter as a separate attachment) can be accessed on the COGR home page at www.cogr.edu (see Latest News!, December 20, 2012 link).

In early January, NIH provided comments to COGR regarding COGR’s “red-lined version” from December 20th. And in mid-January, COGR provided one more set of comments in an effort to remind NIH that any FAQs that address core facilities should be done in a manner that is not overly broad – i.e., the FAQs should be scoped so that they are applicable to NIH core facilities only and are not applied inappropriately to institution-wide service center policies.

COGR responses to NIH were developed by a Workgroup that included members from the COGR Costing Policies Committee and individuals from your institutions who volunteered to be on the Workgroup. In the COGR Holiday Update we recognized those individuals and we are thankful for the expertise contributed by the members on the Workgroup. We will update the membership as soon as learn more on the status of the release of the FAQs.

NIH Salary Limitation Update

Political discussions surrounding Sequestration, the status of the FY2013 Continuing Resolution currently funding the Federal government (and in effect through March 27, 2013), and the new posturing on the FY2014 Federal budget, overshadow any clear direction on the status of the NIH Salary Limitation (which also is applicable to most HHS operating divisions). As we know, the NIH Salary Limitation remains pegged to the Executive Salary Level II (i.e., \$179,700). The EL II will remain applicable, unless Congress changes this statutory requirement in the course of finalizing a FY2013 budget resolution.

As we reported in the February 2013 Update (February 5, 2013), another consideration to the NIH Salary Limitation is the potential for a pay adjustment to all Federal rates of pay. In two Presidential Documents printed in the Federal Register on January 3, 2013 (Vol. 78, No. 2), the President: 1) suspended any pay increases at least through March 27, 2013 (first link), and 2) via Executive Order 13635 (second link), allowed for certain rates of pay to be adjusted after March 27, 2013, effectively resulting in a .5% rate of increase. If EL II remains the benchmark for the NIH Salary Limitation, this would increase the NIH Salary Limitation from \$179,700 to \$180,600.

<http://www.gpo.gov/fdsys/pkg/FR-2013-01-03/pdf/2013-00001.pdf>

<http://www.gpo.gov/fdsys/pkg/FR-2013-01-03/pdf/2013-00002.pdf>

Also looming are rumblings that the Executive Salary Level III could come into play, possibly with the FY2014 Federal budget. With all of this said, any potential adjustments to Federal rates of pay or other changes to the NIH Salary Limitation should be set aside until there is more clarity on the Federal budget situation, and ultimately, NIH. Until then, institutions should continue to operate under last year’s NIH guidance (NOT-OD-12-035), dated January 12, 2012:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html>

Department of Treasury Offset Program (TOP) and Delinquencies with the VA Update

At the COGR Meeting on Friday, February 22nd, we reported on an updated development regarding the TOP. The Association of Government Accountants (AGA) is a membership

organization of more than 16,000, comprised of local finance directors, state auditors, federal chief financial officers, academicians and private sector leaders. We have learned that the AGA has engaged with the Department of Treasury and the Office of Management and Budget (OMB) to address concerns related to the TOP. Our understanding is that several States, including Maryland, Arizona, and Nevada have been active in this project, and issues, such as the recent issue with the Department of Veterans Affairs (VA), will be looked at.

As we reported in the February 2013 Update (February 5, 2013), COGR has engaged with several higher education associations to learn more about possible broad concerns about the TOP, and specific concerns associated with how the VA recently has processed delinquencies through the TOP.

The TOP is a program administered by the U.S. Department of Treasury, Financial Management Service (FMS). Through the interaction of federal databases, payments due to an institution may be reduced, automatically, if the institution is flagged by TOP-FMS-Debt Management Services (DMS) as delinquent on a past due debt. In addition, the General Services Administration (GSA) manages a separate process, the System for Awards Management (SAM). The SAM is designed to check the TOP-FMS-DMS delinquency database, and if there is a delinquency, the SAM may flag institutions with delinquent debt and put a hold on grant awards to those institutions.

The first link below provides a link to a page published by the National Association of College and University Business Officers (NACUBO) and includes a succinct and helpful summary of the Treasury Offset Program, including advice on how institutions can receive help to locate any debt in question and understand the steps needed to resolve related issues. The two links that follow are links to web pages maintained by the TOP-FMS-DMS; one page that describes the TOP and a second page that contains “Common Questions” regarding the TOP. Also note, questions regarding the TOP can be directed to the [TOP Call Center at 1-800-304-3107](http://www.fms.treas.gov/debt/top.html).

http://www.nacubo.org/Business_and_Policy_Areas/Accounting/Accounting_News/More_Institutions_Affected_by_Treasury_Offset_Program.html

<http://www.fms.treas.gov/debt/top.html>

http://www.fms.treas.gov/debt/questions_top_pub.html

Of more urgency is a recent wave of activity associated with delinquencies with the VA. For several COGR institutions, this has resulted in payment offsets on reimbursements related to research awards and/or has triggered holds on the issuance of new awards. While in some cases the debt may be legitimate, changes over the past several years in how the VA has processed GI benefits, as well as some questionable management practices (e.g., incorrect or duplicate offsets, incorrect or inappropriate mailing addresses, unclear audit trails, etc.) by the VA, have contributed to the angst at COGR institutions.

Again, NACUBO (see link below) provides helpful information, this time on VA-specific issues associated with the TOP. In the summary per the link below, NACUBO suggests that schools should email any disputes to VA's Debt Management Center (DMC) at dmcedu.vbaspl@va.gov.

http://www.nacubo.org/Business_and_Policy_Areas/Student_Financial_Services/Student_Financial_Services_News/NACUBO_Workgroup_Meets_with_VA_Staff_Expresses_Concerns.html

If your institution has concerns with the TOP or concerns related to VA-specific issues associated with the TOP and the federal contacts listed above are not helpful, contact NACUBO or COGR staff. Also, we will follow the developments with the AGA and their engagement with Treasury and OMB and keep the COGR membership posted on what we learn.

The NRC Report on Research Universities Update

The October 2012 Meeting Report (November 16, 2012) included a summary of the panel session at the October 2012 COGR Meeting. This session centered on the June 2012, National Research Council (NRC) Committee on Research Universities report: *Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation's Prosperity and Security*. The Full Report and the Summary version are available at the link below.

<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13396>

Recently, NRC Committee members have begun meetings with stakeholders across the country. Dr. Peter Henderson, Director, Board on Higher Education and Workforce, National Research Council, and the individual who directed the Study on Research Universities, shared the following update with COGR:

“We have had two very successful regional meetings so far. In November, the University of Pittsburgh and Carnegie Mellon hosted the first meeting and Chancellor Mark Nordenberg wrote a very nice op-ed in the Pittsburgh Post-Gazette afterwards that summarized the theme of the meeting. See: <http://www.post-gazette.com/stories/opinion/perspectives/mark-a-nordenberg-we-must-invest-in-innovation-to-perpetuate-pittsburghs-progress-669176/>.

On January 16, Vanderbilt hosted the second meeting which began with a terrific panel including [Tennessee] Gov. Haslam, Senator Alexander, Senator Frist, and Chad Holliday. Videos of the sessions at this meeting can be found at: <http://news.vanderbilt.edu/2013/01/nrc-meeting-jan-16/>. More meetings are scheduled for Tucson, Dallas, Detroit, San Diego, and Maryland. And, most importantly, I would like to ask you to save October 10, 2013, for the concluding national conference here in Washington, D.C. We will hold this meeting in the auditorium of the newly renovated National Academy of Sciences building.”

COGR will share periodic updates with the COGR membership as we learn more about the activities and advocacy efforts of the NRC Committee on Research Universities.

Audit Update

In two COGR Updates, late last year (October 2012 Meeting Report - November 16, 2012, and the COGR Holiday Update - December 20, 2012), we included detailed narratives on the activities of two Offices of Inspectors General (OIG) – the Department of Health and Human Services (HHS) and the National Science Foundation (NSF).

In last month's February 2013 Update (February 5, 2013) we reported that since the beginning of the New Year, we are not aware of any new OIG audit developments. For the most part, this remains true. However, one item of note relates to: *NIH - Equipment Claims by Grantees*. According to the HHS OIG Workplan for FY2013 (first link below and Part V, page 87), this continues to be an area of focus for the HHS OIG. Two reports were released last year (second and third link below) and a new report was released last month (fourth link). Per the audit report: *"The \$6,300,860 in costs covered by our review were allowable under the terms of the grants and applicable Federal regulations."*

<https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf>
<https://oig.hhs.gov/oas/reports/region5/51200074.asp>
<https://oig.hhs.gov/oas/reports/region5/51100102.asp>
<https://oig.hhs.gov/oas/reports/region5/51200077.asp>

COGR regularly checks the HHS (NIH) and NSF OIG websites (see links below) and follows other proceedings related to audit.

<https://oig.hhs.gov/reports-and-publications/oas/nih.asp>
<http://www.nsf.gov/oig/auditpubs.jsp>

We always are interested in audit experiences at your institution so that we can update the general landscape for the membership – do not hesitate to contact us. We have the most access to HHS OIG and NSF OIG initiatives, but also are interested in activity related to the OIGs at other agencies, as well as other internal and external audit activities.

Other Costing Developments and Discussions

Below are topics that are either new developments or items we have reported on in the past and continue to follow. If there are cost-related or financial topics that you would like to discuss with COGR, please contact David Kennedy at dkennedy@cogr.edu.

Department of Justice (DOJ) – Concerns with a DOJ Policy Guidance Clarification.

The DOJ, Office of Justice Programs recently released clarifying guidance, subject to the DOJ "Policy and Guidance for Conference Approval, Planning, and Reporting", on the application of F&A rates to subcontracts/subawards and to participant support costs. The clarifying guidance broadens the definitions of the \$25,000 Subcontract/Subaward Limitation and Participant Support Costs, and effectively, restricts application of the F&A rate to allowable costs related to conferences, trainings and meetings. COGR staff is in communication with staff from the DOJ policy office and legal counsel. While similar situations (e.g., NIH/Genomic Arrays) have become common occurrences, the DOJ case could be a good "test case" in the context of the Proposed OMB Guidance and efforts in the Guidance to curtail implementation of arbitrary agency policies.

Accelerating Spending on ARRA Programs: NSF and NIH. Many COGR institutions continue to await guidance from NSF and NIH as to whether or not waivers will be granted, which would allow spending on selected ARRA programs to extend beyond September 30, 2013. Agencies were required to apply to OMB for waivers on affected programs, and OMB

is responsible for granting the waivers. While our understanding is that some ARRA awardees are beginning to receive notification on whether or not waivers have been approved, the community as whole continues to await official guidance from OMB. Until OMB provides direction to NSF and NIH, COGR institutions will remain uncertain as to what to expect. NSF and NIH are diligent in their outreach to OMB and we hope to receive guidance soon.

UPDATE – Treatment of NSF Awards in the SEFA; 2013 A-133 Compliance Supplement. OMB included language in the final draft of the 2012 A-133 Compliance Supplement, which would have required all NSF awards to be reported on the Schedule of Expenditures of Federal Awards (SEFA) as part of the R&D Cluster. COGR was successful in its request to OMB to eliminate the clause. However, this language was included, despite COGR objections, in the 2013 NSF Proposal and Award Policies and Procedures Guide (PAPPG). Consequently, OMB will propose the same language to be included in the 2013 A-133 Compliance Supplement.

COGR has objected to both the NSF and OMB. On principle, we object to the NSF inserting language into their PAPPG, which effectively requires the same language to be incorporated into the A-133 Compliance Supplement. However, we have not formally documented the new burden that may result to COGR institutions (for example, in terms of administrative burden, modifying accounting systems, etc.). Consequently, at this time the basis for our objection is “on principle” only, though “burden” could be documented if we are compelled to do so. *If the requirement to include all NSF awards in the R&D Cluster is problematic to your institution*, please contact David Kennedy as soon as possible.

New GAO Study on Indirect Costs. The U.S. Government Accountability Office (GAO) – an independent, nonpartisan agency that works for Congress to investigate how the federal government spends taxpayer dollars – has begun a study on the indirect costs for National Institutes of Health (NIH) funded extramural research. The study is in response to a request from Senator Jeff Sessions on the Senate Committee on the Budget. Our understanding is that the GAO study will examine: a) the protocol for setting policies for covering indirect costs paid to universities, b) the amounts in indirect costs paid out to the largest universities by NIH, and c) how indirect costs vary across NIH grantees. You may recall the GAO study completed a study in 2010 (see <http://www.gao.gov/products/GAO-10-937>), which was conducted in response to the 2007 DOD indirect cost cap on basic research awards. While the new study appears to be unrelated to the 2010 study, some of the same issues, most likely, will be covered in the new study.

Grant Reporting Information Project (GRIP). COGR has provided updates on GRIP since the October 2012 Meeting Report (November 16, 2012). GRIP is an initiative currently being led by the Recovery Accountability and Transparency Board (RATB) to explore implementing an ARRA-type reporting model for all federal grants (note, contracts are not part of GRIP). The initiative is in a proof-of-concept/pre-pilot stage and should be considered preliminary. The results of the pre-pilot will help determine if GRIP should be expanded to a full pilot. The RATB presented an update at the recent Federal Demonstration Project (FDP) in January, and the RATB expects to release a report that provides findings from the pre-pilot – that report could be available soon. Future development of the GRIP

initiative will be subject to critical review by many stakeholders and possible outcomes cannot be predicted at this time. COGR is paying close attention to all developments related to GRIP, including discussions involving a “Universal Award ID” initiative and issues associated with federal payment systems.

Implementation of the NSF Award Cash Management System (ACM\$). The NSF has shared the following update: “Starting in January 2013, ACM\$ will be implemented early at 38 research organizations. These organizations will begin using ACM\$ after the submission of their final Federal Financial Report to NSF. ACM\$ will be implemented at all NSF awardee organizations in April 2013.” Additional information is available at:

http://www.research.gov/research-portal/appmanager/base/desktop?_nfpb=true&_pageLabel=research_node_display&_nodePath=/researchGov/Generic/Common/WhatisACM.html

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: David Winwood, Chair, University of Alabama at Birmingham; Alexandra McKeown, The Johns Hopkins University; Cordell Overby, University of Delaware; Marianne Woods, University of Texas at San Antonio; Kevin Wozniak, Georgia Institute of Technology; Mark Crowell, University of Virginia; Valerie McDevitt, University of South Florida; Fred Reinhart, University of Massachusetts; John Ritter, Princeton University; Wendy Streitz, University of California;

Startup Act Reintroduced in Congress

We reported in the COGR February Update that a new version of the Startup Act would be introduced in Congress. Startup Act “3.0” (S. 310) was introduced by Sen. Moran (R-KS) on Feb. 13. Co-sponsors are Sens. Blunt, Coons, Klobuchar, and Warner. Similar legislation (H.R. 714) was introduced in the House on Feb. 14 by Rep. Grimm (R—NY), with six co-sponsors.

The bills are virtually identical to the “2.0” version introduced last June. There is much in the proposed legislation that COGR and other higher ed. associations support, including provisions on STEM immigration and favorable tax treatment for startups. However, we remain concerned about provisions in Sec. 8 of the bill on Accelerated Commercialization of Taxpayer-Funded Research. Sec. 8 would create a grant program at the Department of Commerce funded by transfers from federal research agencies of 0.15 percent of their extramural research budgets. Grants would be awarded by Commerce to institutions of higher education for Commercialization Capacity Building and for Commercialization Acceleration initiatives. The latter would be awarded for “initiatives that allow faculty to directly commercialize research in an effort to accelerate research breakthroughs.” Project management costs would be limited under both programs to 10 percent of the grant award. Grant proposals would be reviewed and recommended by the Commerce Advisory Council on Innovation and Entrepreneurship.

The Commercialization Accelerator grants appear to implement the faculty “free agency” concept originally proposed by the Kauffman Foundation. As discussed in previous COGR Updates and Reports, we believe this concept would create significant issues for universities relating to conflict of interest and public accountability. It reflects a misunderstanding of faculty roles and is premised on beliefs about the practices of university tech transfer offices that are not supported by data. It also is inconsistent with the local and regional economic development missions of universities. We also are concerned about the 10% project management cost limitation, and the fact the program would be supported by a “tax” on research agencies.

One possible scenario is that the Startup Act provisions on STEM immigration will be folded into a larger immigration bill, and the Sec. 8 provisions will not advance further. However, we will continue to discuss our concerns with policymakers in the legislative and executive branches in conjunction with other higher ed. associations, particularly if Startup Act 3.0 moves forward.

COGR Comments on Proposed HHSAR DEC Clauses

The February Update mentioned that the Department of Health and Human Services (HHS) had proposed to add two new clauses to its Acquisition Regulations (HHSAR), covering Patent Rights and Data Rights in Exceptional Circumstances. The clauses would be used in contracts where HHS has approved a Determination of Exceptional Circumstances (DEC) to provide contractors with other than normal Bayh-Dole invention rights (*78FedReg2229*; 1/10/13).

COGR submitted comments to HHS on the proposed clauses on March 8. Our comment letter noted a general concern and a number of specific comments. As a general comment, we noted that the basic premise of the Bayh-Dole Act and implementing regulations is that elimination or restriction of a contractor’s right to retain title to subject inventions is intended only in the event of “exceptional circumstances.” Written case-by-case determinations and justifications are required. We expressed the view that providing a “class” deviation from Bayh-Dole in the HHSAR appeared inconsistent with the intent to limit the use of exceptional circumstance deviations through requiring individual case-by-case justifications. The present practice of the use of individual Federal Acquisition Regulations (FAR) deviations tailored to the specific DEC circumstances is more consistent with the objectives of the Bayh-Dole Act.

Among the specific concerns mentioned was that 1) the proposed patent rights clause defines three categories of Subject Inventions but refers to the DEC(s) for the definition, which presumes DEC(s) will all contain the same three categories; this appears inappropriate for a HHSAR clause as DEC(s) may vary in this regard; 2) a number of problematic terms and definitions, some of which appear inconsistent with NIH policies (e.g. for Class I “Subject Inventions” nonprofit institutions may retain a license solely to practice the invention for noncommercial “internal” research); and 3) a six months restriction on publication in the proposed rights in data clause and a requirement for approval of the HHS contracting officer to assert copyright in all data other than journal articles.

A copy of the comment letter is posted on the COGR website.

AIA - PTO Publishes Final Implementation Rules and Examination Guidelines

On February 14 the U.S. Patent and Trademark Office (PTO) published final rules of practice to implement the “First Inventor to File” provisions of the America Invents Act (AIA) and companion Examination Guidelines for patent examiners (78FR11024; 78FR 11059). The new First Inventor to File system is effective for patent applications submitted on or after March 16, 2013.

Our concerns with the rules initially proposed were discussed in the COGR October 2012 Update. We noted a major concern with the proposed Examination Guidelines involving the one year grace period for scientific publications prior to filing of patent applications. In order for the grace period to apply, the proposed Guidelines stated that the subject matter disclosed in an intervening disclosure must be identical to the subject matter of the original disclosure. Otherwise the intervening disclosure would be considered disqualifying prior art to the patent application. The inventor himself or herself could inadvertently cause loss of the grace period through a subsequent non-identical publication or other disclosure or a third party could do so. We also noted concerns about treatment of authorship of grace period disclosures in the proposed Guidelines. In comments to PTO dated October 5, COGR and the five other higher ed. associations that have worked together on patent reform strongly objected to these provisions. We also commented that non-public offers for sale such as under confidential offers to license university technologies should not be prior art.

In the final rules PTO has clarified that secret sales activities do not qualify as prior art if they occur under confidentiality or non-disclosure agreements (thus overruling former case law based on the old *Metallizing Engineering* case). PTO also backtracked from the provision in the proposed Guidelines that a grace period publication having more authors than inventors listed in the subsequent patent application would cause automatic rejection of the patent application. Instead, the final rules state that when there are additional named individuals on a prior art publication as compared to named inventors, applicants must show that the additional named authors did not contribute to the claimed subject matter of the patent application. The rules of practice discuss mechanisms for filing affidavits or declarations to establish this. (More inventors than authors of a grace period publication is not a problem). Thus it appears we had two “wins” with regard to our comments on the proposed rules.

However, on the major issue of the grace period, unfortunately the final Guidelines do not adequately address our concern. PTO has made the grace period slightly less narrow. The final Guidelines state that for the grace period to continue to apply it is not necessary for the intervening disclosure to have been disclosed in the same manner. Thus the inventor may have publicly disclosed the subject matter originally via a slide presentation at a scientific meeting; then made an intervening disclosure in a journal article. There also is no requirement that the intervening disclosure be made verbatim or using the same words. Finally, if the subject matter of the intervening disclosure is simply a more general description of the subject matter previously disclosed by the inventor, the grace period applies to the intervening disclosure. The example given is when an inventor publicly discloses a species and a subsequent grace period disclosure discloses a genus, the subsequent disclosure is not prior art. However, the converse is not true: if an inventor publicly discloses a genus, and a subsequent intervening grace period disclosure discloses a species, the intervening disclosure is prior art. Otherwise, PTO has

reiterated that for the grace period to apply there cannot be variation in the subject matter disclosed; the subject matter of any disclosures must be conceptually the same with no additions or modifications for the grace period to apply.

PTO received a great many comments on the proposed rule with regard to the grace period. According to the Federal Register notice, university and non-profit groups as well as the startup inventor community and the Small Business Administration all expressed concerns with PTO's interpretation of the grace period provisions of the AIA. Discussions with PTO indicate that there was an approximate 50/50 split in comments received on this issue. However, PTO adopted as its final interpretation the views expressed by the 50% of comments adverse to our position.

We believe PTO's interpretation is wrong and contrary to the legislative history, which in our view contemplated no change in the broad pre-AIA grace period. However, it appears we will need either legislative changes or court decisions to reverse PTO's interpretation. (The imprecision in the Guidelines may invite challenges to patents on prior art grounds either through *inter partes* administrative proceedings or litigation). Except for disclosures among parties subject to confidentiality agreements or joint research agreements as defined in the AIA (and the predecessor CREATE Act), any disclosures of potentially patentable subject matter by university inventors appear problematic and may not be subject to grace period protection. This is not necessarily a new problem since the grace period always has been available only for U.S. patent applications. However, only about a quarter of U.S. university patents currently also are filed for protection in other countries. Regardless of where patent applications may be filed, universities now may need to assume grace period protection may not be available for disclosures by university inventors. The result is a potentially chilling effect on scientific publications. Conversely, given that publishing tends to be a higher priority in the academic community than patenting, an increased number of university innovations may not receive the benefit of patent protection and be commercially developed. These are exactly the outcomes we had sought to avoid by seeking to preserve the broad grace period throughout the long patent reform process.

COGR Seeks Clarification of PTO Rules on Micro Entity Patent Status

We discussed the final rules implementing the new AIA micro entity patent status in the February Update. Micro entity status provides for a 75% fee reduction in patent filing and other patent fees. We noted ambiguity in the final rules about the eligibility of institutions of higher education or their inventors to claim micro entity status.

The COGR CIP Committee discussed this issue with the PTO Patent Reform Coordinator. The ambiguity involves the meaning of "applicant" in Section 1.29(d) (implementing 35 U.S.C. 123(d) of the AIA) in the final PTO rules. We had understood that 123(d) provided for eligibility of institutions of higher education to claim micro entity status. However, the PTO rules state that the criteria for eligibility would not normally be met by institutions of higher education that are themselves applicants. To claim this status under 1.29(d), applicants must certify that 1) their employer from which the applicant obtains the majority of his/her income is an institutions of higher education or 2) that the applicant has assigned, granted, conveyed or is under an obligation by contract or law to do so, a license or other ownership interest in the patent application to an institution of higher education.

The discussion clarified that so long as the university inventors themselves are the patent applicants (and meet one or the other of the above criteria), they may claim micro entity status even if the university (or its affiliated research foundation) manages the patent process and pays the fees. This apparently would be the case even where the inventor has assigned the invention (and subsequent patent) to the university (or where the ownership interest has automatically passed to the university with a present assignment under the decision in the *Stanford v. Roche* case). In many cases patent applications are filed by universities in the name of the inventor(s). It appears in such cases that micro entity status with its 75% fee reduction would be available.

The PTO Coordinator asked us to provide hypotheticals with different fact patterns that could be used in PTO training of examiners and also for further clarification of the issues that might arise in this area. We have done so, providing a number of hypotheticals including the *Stanford v. Roche* situation and where inventions have been assigned by university employees to a separate university research foundation.

We are aware that university counsels have reached varying conclusions with regard to micro entity status eligibility. We are not entirely sure of the correct interpretation. Universities in any event remain eligible for “small entity” status with its 50% fee reduction. We will keep the COGR membership informed of any further PTO interpretations or advice with regard to micro entity status.

PTO Seeks Input on Patent Harmonization

On February 1 the Patent and Trademark Office issued a notice of public hearing and request for stakeholder comment on several matters relating to international harmonization of substantive patent law (78FR7411). Information was sought on the grace period; publication of applications; treatment of conflicting applications; and prior user rights. Included with the notice was a link to a downloadable questionnaire on these issues, to be submitted electronically. In addition, a public hearing on these issues is to be held March 21 at PTO, which will be webcast at www.uspto.gov/ip/global/aia_harmonization.jsp.

The questionnaire cannot readily be completed by COGR or other higher ed. associations, since it asks for information about specific matters and specific experiences with these issues. However, we encouraged CIP committee member institutions to complete and submit the questionnaire. Some have done so. In addition AUTM was asked by PTO to provide input. We believe AUTM is better situated to provide this kind of input for the university community. We have discussed with AUTM possible approaches to the input for the public hearing. One point that might be made is that with the U.S. move to a first to file patent system there has been an expectation that other countries would adopt a grace period similar to the U.S. However, PTO’s narrow interpretation has muddied the waters. For the reasons discussed in 3.a. above there is a real question as to how effective the U.S. grace period now is. Given that, it’s not clear what we can or should expect other countries to do. The PTO interpretation also appears highly disadvantageous to U.S. universities, as discussed above.

PTO Requests Comments on Small Claim Patent Proceeding

On December 1 the Patent and Trademark Office asked for comments as to whether the U.S. should develop a small claims proceeding for patent enforcement (77FR74830). PTO asked whether there was a need or desire for this type of proceeding, the circumstances in which it might be needed, and what features or characteristics the proceeding should possess. On the latter, the PTO notice asked for input on 19 specific aspects of such a proceeding.

The concept of a U.S. patent small claims court has been discussed for over 20 years, and endorsed by various groups. However, there appears perhaps a surprising split of opinion in the university patent community about the advisability of establishing such a proceeding. Some strongly back the concept, believing it would benefit small entity inventors and small university tech transfer offices with limited budgets to sue infringers. Others, however, believe that it could be used to harass universities and that it could be a disincentive to settle infringement litigation. COGR has not taken a position on the matter, given the diversity of opinion in the community and the fact it involves matters of patent practice. As with the harmonization issues, we believe AUTM is best suited to address this matter.

A Patent Small Claims Symposium was held in Chicago on February 28, unfortunately in direct conflict with the AUTM Annual Meeting. We understand the symposium was attended by judges, practitioners, industry and academic representatives, and PTO officials, and that much information was presented. Given the interest, PTO has extended the deadline to submit comments to April 30.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: James Tracy, Chair, University of Kentucky; Pamela Caudill, Harvard University; Michelle Christy, Massachusetts Institute of Technology; Kelvin Droegemeier, University of Oklahoma; Michael Ludwig, Purdue University; Susan Sedwick, University of Texas, Austin;; Michael Amey, The Johns Hopkins University; Kathleen Delehoy, Colorado State University; Suzanne Rivera, Case Western Reserve University

NSF Automatic Compliance Checking

Beginning March 18, 2013, the NSF will begin automated compliance checking of all required sections of proposals submitted in FastLane and through Grants.gov. **All required sections must be completed or addressed in some manner in the application or FastLane will block submission. If a section is not applicable for any reason, investigators must insert a page/section that states NOT APPLICABLE.**

Principal investigators (PIs) will receive a warning message if any of the GPG-required sections are missing, however, the PI will still be able to submit the proposal to the organization's Sponsored Project Office (SPO). If the SPO attempts to submit proposal that is missing any of the GPG required sections, they will receive an error message identifying the missing section(s),

and FastLane will prevent submission to NSF. After obtaining all required sections, the SPO may submit the proposal to NSF in accordance with the established deadline date policy.

The required sections of a proposal include: Project Summary; Budget Justification; Project Description; Current and Pending Support; References Cited; Facilities, Equipment and Other Resources; Biographical Sketch(es); Data Management Plan; Budget; and Postdoctoral Mentoring Plan (if applicable). All these required sections are described in the proposal preparation requirements in the NSF *Proposal and Award Policies and Procedures Guide* (PAPPG) (Chapter II.C.2 of the Grant Proposal Guide (GPG)).

It is **very important to note** that some proposal instructions for programs like conferences, symposia or workshops; international travel grants may deviate from the GPG instructions. **If the submission instructions do not require one of the above sections to be provided, proposers will need to insert text or upload a document in that section of the proposal that states, “Not Applicable.” Without entering something for each section, the proposal will not be accepted by FastLane.**

Additionally, proposers providing Biographical Sketches and/or Current and Pending Support information for Principal Investigators (PIs), co-PI(s) or Senior Personnel **in a single PDF file associated with the PI**, must insert text or upload a document in that section of the proposal that states, “Not Applicable,” for any co-PI or Senior Personnel so that FastLane will accept the proposal.

OSTP Proposed Dual Use Research Policy

The Office of Science and Technology Policy (OSTP) announced a proposed policy for *Institutional Oversight of Life Sciences Dual Use Research of Concern* in the Federal Register on February 22, 2013 (78FR12369). Comments are due April 23, 2013. The Federal Register notice presents a series of 16 questions concerning the proposed policy (available on the Department of Health & Human Services [HHS] Science Safety Security (S3) website: <http://www.phe.gov/s3/dualuse/Pages/default.aspx>). The proposed policy addresses information derived from work with the 15 select agent and toxins and seven threatening outcomes or effects of research conducted with those agents and toxins that were identified in the March 29, 2012 Federal policy. It establishes institutional review and oversight requirements at institutions that accept Federal funding for such research.

You will recall in our discussion at the June 2012 meeting (slides available on the COGR website) that dual use research of concern (DURC) is a smaller subset of dual use research defined as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.” Under the proposed policy, institutions conducting research with the covered agents or toxins would be required to review the research and develop, if appropriate, risk mitigation plans. These new requirements address the risks of dual use research not addressed under existing Federal regulations or guidelines including the Centers for Disease Control and US Department of Agriculture select agents and toxin regulations, Select Agents and Toxins Program (42 CFR part 73, 9 CFR part 121, and 7 CFR part 331); the National Institutes of Health

(NIH) *Guidelines on Research Involving Recombinant DNA Molecules* and CDC/OHSA Biosafety in Microbiological and Biomedical Laboratories (BMBL). These current regulations and guidelines govern the safety and security of the agents themselves. This policy is focused on the management of the information or outcomes of the research.

In the questions posed in the Federal Register notice, OSTP seeks specific information including: whether the scope (should it be broader) and applicability (all research, federally and non-federally sponsored) are appropriate; alternatives to the various administrative requirements; whether the policy can be successfully integrated with other oversight processes to reduce burden including using the currently constituted Institutional Biosafety Committee as the institutional review body; the processes for making and reporting the determinations; coordination between the federal policy and institutional policy; and the need for additional guidance. OSTP is particularly interested in the observations on the proposed policy from institutions currently working with the agents/toxins.

COGR will respond but it will be important for institutions currently using the listed agents/toxins to provide comment as well – either to COGR or directly to the federal government. We will keep the membership informed as we craft COGR's response and we welcome your comments and observations (cblum@cogr.edu).

NABR Survey to Estimate Impact of Possible AWA Change to Cover Rats, Mice and Birds

Given the introduction of a bill in the U.S. House at the end of the last Congress (H.R. 6693) that would have regulated rats, mice and birds used in research under the Animal Welfare Act (AWA), the National Association for Biomedical Research (NABR) has prepared a confidential survey to assess the impact of inclusion of rats, mice and birds under the AWA and to estimate the overall cost of compliance. In addition to answering questions from members of Congress and the public related to regulatory and financial burden, this survey will allow NABR and other Washington-based association including COGR to make informed estimates of the number of these species currently in U.S. research. NABR would like to have the most complete response possible from the research community – your institution does not need to be a NABR member to respond. To assist us, COGR encourages you to take the time to complete this survey.

The survey is posted to the NABR website at: http://www.nabr.org/uploadedFiles/nabrorg/Content/Hosted_Files/NABR_Survey.xls **Please complete and return to info@nabr.org.** (Do not return it to COGR.) Any questions or comments should be directed to NABR at info@nabr.org.

OSTP Directs Agencies to Increase Access

In a memorandum issued on February 22, 2013, John Holdren, Assistant to the President for Science and Technology and Director of the White House Office of Science and Technology Policy (OSTP) directed Federal departments and agencies with over \$100 million in annual research and development expenditures to come up with a plan to *Increase Access to the Results of Federally Funded Scientific Research*. Specifically, Federal agencies are to develop plans that provide greater public access to peer-reviewed publications and digital data. Draft plans are due to OSTP within six months (August/September 2013) and, following review by

OSTP and the Office of Management and Budget (OMB), agencies are directed to develop final plans in a transparent process that solicits the views of the agencies' stakeholder communities.

Holdren's memorandum outlines the general underlining policy principles – to mobilize research results “for re-use through preservation and broader public access – and establishes various elements to be addressed in agency plans with the general parameters for each outlined. For example, agencies are directed to take advantage of existing archival resources for publications and data and improve the public's ability to find, search, and analyze publications and data from federally funded research. Of greater interest to agency awardees, the plan must address the notification of awardees of the obligations and include a strategy “for measuring and, as necessary, enforcing compliance with the plan.” Examples of notification approaches include guidance, conditions of an award and/or regulatory change – depending on the nature of the agencies' agreements with recipients.

In the area of publications, the goal is long-term preservation and access to unclassified peer-reviewed publications. OSTP outlines some parameters for achieving that objective. The plan must provide easy long-term access to the appropriately attributed final peer review manuscript or publication within twelve months of publication in an interoperable data format that anticipates future technologies.

For scientific data in digital formats, the goal of long-term preservation and easy access to unclassified material remains the same. Scientific data is defined using a slightly expanded definition from the Office of Management and Budget's (OMB) Circular A-110 [additions added in brackets] - research data is “the [digital] recorded factual material commonly accepted in the scientific community as necessary to validate research findings [including data sets used to support scholarly publications], but [does] not [include laboratory notebooks] preliminary analyses, drafts of scientific papers, plans for future research, peer review [reports], communications with colleagues [or] physical objects (e.g., laboratory samples).” Ensuring that agencies respect this definition of research data will be key factor in avoiding policies that require differing responses that are not a result of differences in disciplines.

The plan for scientific data must protect confidentiality and personal privacy; recognize proprietary interests, confidential business information and intellectual property rights; and “preserve the balance between the relative value of long-term preservation and access and the associated cost and administrative burdens. “Recipients can be expected to develop data management plans with the costs for data management an allowable cost on proposals.

The development of this government-wide directive has more than three years. In response to OSTP's requests for comment on varying public access strategy in 2009 and 2011, COGR has consistently raised the inherent challenge in the nature of the institution's relationship – or lack thereof – to the process of publication. As the recipient of federal awards, institutions will be the responsible party to ensure compliance with any government-wide requirement directed at achieving public access. We have noted that it is very difficult for institutions to effectively track compliance with these obligations. Publications that result in whole or in part from a federally sponsored award may appear several years after the completion of the funded research. The investigator/author may have moved to a new institution in the intervening period. Tracking

publications from collaborative research with investigators/authors from more than one institution is a monumental task.

We have raised concerns about the burgeoning costs as well. As NIH moved forward with this policy, investigators discovered a shifting of journals' business models from subscriptions to publication costs to the author. There are direct charges for the submission of articles – “article processing charges” that journals charge to authors for public access for a single article with some as high as \$3,000. NIH reminded the community that publication charges are an allowable expense against a grant but, in many cases, publications are accepted after a grant has closed. Charging these publication costs to a grant, if possible, would result in a real reduction in funds available to conduct the research itself. Absent a government-wide investment to support the costs of publication, a government-wide policy requiring public access to publications becomes an additional unfunded mandate for the research community.

With regard to scientific data specifically, we worried about preserving rights for the original investigator to use and mine the data for future avenues of research. Noting the value of research data as a source for inventions, publications, and as the origin for expending existing and creating new businesses, we argued that the individual most capable and most interested in using the data is the person who created it and that it would be a mistake to jeopardize the ability of that individual scientist or investigator to exploit the potential of the data.

In addition to concerns about ensuring first use and intellectual property protections – particularly as changes to the patent regulations shift from first to invent to first to file – COGR cautioned OSTP that establishing new data standards may require a significant investment in re-formatting of data.

There is no specific timeline for implementation of the final plans (after OSTP/OMB review of the draft plans). We will need to monitor the research agencies and follow their proposed implementation plans to ensure they meet the parameters outlined by OSTP.